Remarks/Arguments:

Status of Claims

Claims 15-26 and 39-80 are in the application.

By way of this amendment, claims 17-26 and 55-80 have been canceled without prejudice, claim 15 has been amended and new claims 81-107 have been added.

Upon entry of this amendment, claims 15, 16, 39-54 and 81-107 will be pending.

Summary of the Amendment

Claim 15 has been amended to set forth the route of administration or the claimed methods as sublingual. administration. Claim 15 has also been amended to correct the obvious typographical error referred to in the claim objection in the Official Action. Support for the amendment is found throughout the specification and claims as filed. No new matter has been added.

The new claims that have been added define specific embodiments of the present invention. Each of the new claims depends directly or indirectly on claim 15.

New claims referring to cytokine and lymphokine genes which may be administered in methods according to the invention are described on page 9 of the specification.

Support for each of the new claims is found throughout the specification. No new matter has been added.

Response Deadline

Applicants note that the Official Action summary indicates the period to respond is one month. Given the nature of the action, this appears to be a typographical error which was intended to be three months.

Priority

It is asserted that Applicants have not included appropriate reference to priority applications. Applicants urge that such cross reference section was added by preliminary amendment when the application was originally filed on February 14, 2002. Applicants have updated the cross reference section by way of this amendment. Applicants have complied with the requirements for claiming priority to the parent application under 35 USC 120. Applicants respectfully request confirmation by the Office in this regard.

Claim Objection

Claim 15 has been objected to for inclusion of an obvious error. Applicants have amended claim 15 to correct the error. The grounds for the objection are thereby removed.

Double Patenting

The claims have been rejected over the judicially created doctrine of obvious-type double patenting as being unpatentable over claims 1-4 and 7 of U.S. Patent No. 6,348,449. Applicants shall file a terminal disclaimer as appropriate upon identification of allowable subject matter. Applicants invite the Examiner to telephone Applicants' undersigned representative at 215-665-5592 to arrange to have such terminal disclaimer transmitted to the USPTO be telefax upon such identification of allowable subject matter.

Claim Rejection – 35 USC §102(e)

Claims 15-22, 24-26, 39-41, 45-47, 51, 55, 59, 60, 64, 68, 69, 73 and 77 have been rejected under 35 USC 102(e) as being anticipated by Carson (US Patent No. 5,679,647).

Claim 15 has been amended to limit the route of administration to sublingual. Each claim depends from claim 15 directly or indirectly and thereby contain the element of sublingual administration.

Carson (US Patent No. 5,679,647) neither discloses nor suggests sublingual administration. Carson (US Patent No. 5,679,647) does not disclose each and every element of the claims. Accordingly, Carson (US Patent No. 5,679,647) does not anticipate the claims as amended.

Applicants respectfully request that the rejection of claims under 35 USC 102(e) as being anticipated by Carson (US Patent No. 5,679,647) be withdrawn,.

Claim Rejection – 35 USC §102(f)

Claims 15-26 and 39-80 have been rejected under 35 USC 102(f) in view of US Patent No. 6,348,449. It is asserted that the claims have a different inventive entity and thereby require a statement of common ownership.

Applicants' records indicate that the inventive entity is identical between the present application and US Patent No. 6,348,449, which is the parent application to which the present invention claims priority. The application and patent both name Weiner, Wang and Ugen as co-inventors. Applicants respectfully request confirmation that the Office has the same information. Moreover, the applications are commonly owned.

Applicants respectfully request that the rejection of claims under 35 USC 102(f) be withdrawn.

Claim Rejection – 35 USC §103

Claims 15 and 23 have been rejected under 35 USC 103(a) as being unpatentable over Carson (US Patent No. 5,679,647) in view of Carson et al. (US Patent No 5,804,566).

As noted above, Carson (US Patent No. 5,679,647) neither discloses nor suggests sublingual administration.

Carson (US Patent No. 5,804,566) refers to the failure to induce allergen tolerance by sublingual administration of allergen.

It is asserted that the combination render the claims invention obvious because Carson (US Patent No. 5,804,566) teaches that sublingual routes of administration were known and therefore once skilled in the art would combine the reference to eliminate the deficiency in Carson (US Patent No. 5,679,647) to arrive at the claims invention.

Applicants respectfully disagree. Applicants urge that each patent, alone and particularly when taken in combination teach away from the present invention. Carson (US Patent No. 5,679,647) conspicuously omits sublingual as a route of administration. When taken in view of Carson (US Patent No. 5,804,566), one skilled in the art would conclude that sublingual is not among the acceptable mucosal routes of delivery.

Contrary to the assertions in the Official Action, there is nothing in the to suggest that one skilled in the art would be motivated to use a route of administration disclosed as a generally known route of administration but which is conspicuously omitted from the list of routes of administration taught by the prior art to be useful in nucleic acid delivery. Given the extremely limited number of

mucosal tissues specific routes and the teachings of the usefulness of all but one, the combination of references would lead one skilled in the art to conclude not to use sublingual administration in nucleic acid delivery.

Applicants respectfully request that the rejection of claims under 35 USC 103(a) as being unpatentable over Carson (US Patent No. 5,679,647) in view of Carson (US Patent No. 5,804,566) be withdrawn.

Claims 15, 16, 18, 19, 21, 22, 24, 26, 39-43, 45-49, 51-53, 55-57, 59-62, 64-66, 68-71, 73-75 and 77-79 have been rejected under 35 USC 103(a) as being unpatentable over Carson (US Patent No. 5,679,647) in view of Wang et al. (PNAS 1993:41656-60).

Carson is discussed above.

Wang discloses administration of a plasmid encoding HIV gp160 in an HIV vaccine.

It is asserted that it would have been obvious to replace the influenza antigen disclosed in Carson with the HIV antigen disclosed in Wang to arrive at the present invention.

Applicants respectfully disagree. As noted above, Carson (US Patent No. 5,679,647) neither discloses nor suggests sublingual administration. Nothing in Wang makes up for this deficiency. The combination of Carson and Wang do not render the claimed invention obvious.

Applicants respectfully request that the rejection of claims under 35 USC 103(a) as being unpatentable over Carson (US Patent No. 5,679,647) in view of Wang be withdrawn

Conclusion

Claims 15, 16, 39-54 and 81-107 are in allowable form An indication that the claims are allowable is earnestly solicited.

Respectfully submitted,

Dated: June 4, 2004
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